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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,087	02/19/2004	Stephen T. Foley	P0024937.11US	4761
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924				
EXAMINER				
HOLMES, REX R				
ART UNIT		PAPER NUMBER		
3762				
NOTIFICATION DATE		DELIVERY MODE		
10/04/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/782,087

Applicant(s)

FOLEY, STEPHEN T.

Examiner

REX HOLMES

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-18, 20-31 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-26, 37 and 38 is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-18, 27-31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9, 11-18, 27-28 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 recites the limitation "a plurality of stimulation vectors" in lines 15-16. There is insufficient antecedent basis for these limitations in the claim. These terms are inferentially included. It is unclear if the applicant is positively reciting the elements. It is suggested to first set forth that the plurality of stimulation electrodes provide a plurality of different stimulation vectors. It is noted that support will be needed to be pointed out in the originally filed written description.

Claim Objections

4. Claim 1 is objected to because of the following informalities: Claim 1 is objected as no element has been set forth to create/generate the stimulation that is delivered.
5. Claim 5 is objected to because of the following informalities: Claim 5 is objected as the claim states that the stimulator is a microprocessor; it is unclear how a microprocessor performs the functions of a stimulator.
6. Claims 6 and 11 recite the word "may". This is vague as it does not state that the claim actually has to include the limitations. It is noted that the use of may is indefinite.

7. Claim 18 is objected to because of the following informalities: The claim recites the following limitation, "a temporal offset". This is vague as it is unclear what the temporal offset is offset from?
8. Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-9, 11-18, 27-31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cigaina (U.S. Pat. 5,423,872) in view of Douglas (U.S. Pat. 5,292,344) and Gordon et al. (U.S. Pat. 6,684,104 hereinafter "Gordon").
11. Regarding claims 1-3, 7-9, 29, 31 and 34-36, Cigaina discloses a gastric pacemaker that senses particular electric activity and then provides "on demand" stimulation (Col. 3, ll. 41-45). Cigaina further discloses that the system stimulates to disrupt normal slow waves and prevent emptying of the stomach (Abstract; Col. 1, line 60 to Col. 2, line 12; Col. 2, line 65 to Col. 3, line 7; Col. 3, ll. 20-51; Col. 4, ll. 8-10).
12. Regarding claim 5, Cigaina discloses that the stimulator is programmable and thus inherently has a programmable controller (Col. 3, ll. 41-45).

Regarding claims 1-3, 5, 7-9, 27-29, 31 and 34-35, Cigaina discloses a system that senses and then disrupts normal activity, it is silent as to if the gastric pacemaker includes multiple electrodes. However, Douglas discloses a gastric pacemaker that

includes multiple electrodes for sensing and stimulating that are located through the stomach and connected to sensing and stimulation channels (Figs. 1 & 2A). Douglas further teaches how the electrodes are connected to the gastric pacemaker on one end and the stomach wall on the other end (Fig. 2A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal pacemaker of Cigaina with the multiple electrode gastrointestinal pacemaker of Douglas in order to provide the predictable results of increasing the sensing and stimulation sites to provide increased control. Cigaina in view of Douglas discloses the claimed invention but fails to teach that the system can switch between any of a plurality of vectors. However, Gordon teaches that it is known to use a gastric stimulator with multiple electrodes that can implanted in a large patch and then is capable of switching between the various electrodes to form vectors that stimulate the best based on sensed activity as taught in (e.g. Col. 16, ll. 16-40; Col. 20, ll. 25-46) to provide the physician with the time saving task of installing individual electrodes, thereby reducing the time required for electrode installation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes and processor as taught by Cigaina in view of Douglas, with an electrode patch with a processor that switches between stimulation vectors as taught by Gordon, since such a modification would provide the predictable results of having a processor with the flexibility of selecting vectors for providing increased flexibility of allowing for various vectors from preinstalled electrodes so that the physician does not have to remove and install various electrodes.

13. Regarding claims 4, 6, 11-18 and 30, Cigaina in view of Douglas discloses a gastrointestinal stimulation device as described in detail above, and further discloses that the stimulator is triggered on classified events and the stimulation is delivered to the stomach in the areas where the intrinsic activity was sensed. But, Cigaina in view of Douglas does not teach a power conservation condition, a telemetry system or a way to save sensed data. However, Gordon teaches a power conservation condition that takes into account the time of day and in the absence of a triggering activity (Col. 2, ll. 62-67 and Col. 3, ll. 1-5). Gordon further discloses that the controller contains an internal storage device and the data can be telemetered using an inductive coupling methodology or radio communication methodology (Col. 15, ll. 1-9; Col. 10, ll. 44-58).

14. Regarding claims 6 and 11-13, Cigaina in view of Douglas discloses the claimed invention except for the powersave features. However, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the gastrointestinal stimulation device of Cigaina in view of Douglas with the power conservation of Gordon in order to provide the predictable results of increasing the life of the stimulation device, increasing the life of the battery, and to increase the overall quality of life of the patient.

15. Regarding claim 36, Cigaina in view of Douglas and Gordon discloses a system that senses and then disrupts normal activity, but it is silent as to if the gastric pacemaker withholds stimulation when abnormal activity is present. However, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Cigaina in view of Douglas in view of Gordon,

with a stimulator that only stimulates when normal waves are present since it was known in the art that a system that disrupts normal activity is not needed when normal activity is not present and thus withholding stimulation during unnecessary times provides the predictable results of disrupting normal activity without unnecessarily delivering stimulation to the patient in order to further provide the predictable results of increasing the life of the stimulation device, increasing the life of the battery, and to increase the overall quality of life of the patient.

16. Regarding claims 14-18, Cigaina in view of Douglas and Gordon discloses the claimed invention except for explicitly stating that the stimulation is offset or direct. However, Douglas discloses that multiple electrodes and sensors positioned around the stomach with a programmable stimulator as set forth in (e.g. Figs. 1 & 2A) to provide direct stimulation to the stomach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation as taught by Cigaina in view of Douglas and Gordon, with variable stimulation methods since such a modification would provide the predictable results of stimulating the stomach directly or indirectly to provide increased disruption of the normal waves.

17. Regarding claim 30, Cigaina in view of Douglas discloses the claimed device including memory (Douglas 430, 440, 450), but fails to disclose that the device maintains a history of predecessor events. However, Gordon teaches a device that contains memory for storing the stimulation data so that it can be reviewed later to help provide better stimulation (Col. 10, l. 59 to Col. 11, l. 17; Claims 6, 8, 14 and 32). It would have been obvious to one having ordinary skill in the art at the time the invention

was made to have provided the gastrointestinal stimulation device of Cigaina in view of Douglas with the memory storage of Gordon in order to provide the predictable result of a history of stimulation events for review to provide improved stimulation in the future.

Allowable Subject Matter

18. Claims 20-26 and 37-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

19. Applicant's arguments with respect to claims 1-9, 11-18, 20-31, 33-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3762
/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762